

PERKINS COIE LLP

101 JEFFERSON DRIVE • MENLO PARK, CALIFORNIA 94025-1114

TELEPHONE: 650 838-4300 • FACSIMILE: 650 838-4350

#10  
nb  
05/16/02

RECEIVED

MAY 09 2002

TECH CENTER 1600-2900

April 22, 2002

COPY OF PAPERS  
ORIGINALLY FILED

Box: Comments  
Commissioner for Patents  
Washington, D.C. 20231

Dear Commissioner of Patents:

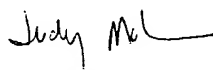
This letter concerns recent observations on Restriction Requirements and Species Elections. It is my observation that the patent office is imposing restrictions liberally, in biotechnology and in other art groups. As you can appreciate, numerous restrictions in a single application places an undue economic burden on patent applicants to obtain patent protection for their invention. Accordingly, I respectfully ask that the PTO position on Restriction and Species Election be clarified for the public and for those practicing before the PTO.

With respect to the biotechnology industry, it is my understanding that MPEP 803.04 (corresponding to 1192 O.G. 68, November 19, 1996) sets forth the current regulation. Based on this, it is my further understanding that "normally ten sequences constitute a reasonable number for examination purposes." However, the Examiners are now as a matter of course requiring election of a single sequence for examination. By way of an example, I attach a copy of a restriction requirement dated March 21, 2002. In the application, a dependent claim set forth seven protein sequences in a Markush group. The sequences are related in that six of them are fragments of one sequence. Thus, the sequences are both structurally and functionally related. Nevertheless, the Examiner required election of a single sequence.

With respect to art units other than biotechnology, I attach a copy of a restriction requirement dated September 10, 2001. Here, the claims in the application are directed to a lipid vesicle composition for administration of a protein, interferon- $\alpha$ . The Examiner required election of a (i) phospholipid for forming the lipid vesicle; (ii) a species of interferon- $\alpha$ ; and (iii) an acylated amino acid that is entrapped in the lipid vesicles. It is difficult to understand the restriction to phospholipids for forming the lipid vesicle, since (1) no dependent claim called out a phospholipid; and (2) the phospholipids known for use in the art are not patentably distinct from one another.

As a practitioner before the PTO, I would be better able to serve my clients if the restriction practice were clarified. I would be happy to discuss this further, and if you have any questions please do not hesitate to contact me.

Very truly yours,



Judy M. Mohr, Ph.D.  
Patent Agent, Reg. No. 38,563

JMM/jlm  
Enc.